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# Massachusetts Department of Public Health

## **Draft Proposed Amendments to 105 CMR 721.000 Standards for Prescription Format and Security in Massachusetts**

**Public Health Council  
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# Summary of Regulation

105 CMR 721.000, *Standards for Prescription Format and Security in Massachusetts:*

- Outlines Drug Control Program (DCP) format and security requirements for valid prescriptions in Massachusetts;
- Provides special procedures for emergency prescription of Schedule II controlled substances; and
- Establishes requirements for issuing and dispensing partial prescriptions.

# Summary of Amendments

The proposed amendments to this regulation implement provisions of Chapter 208 of the Acts of 2018 (the CARE Act), which:

- Update partial fill requirements for Schedule II prescription, consistent with federal opioid legislation (The SUPPORT Act).
- Require all prescriptions for controlled substances and devices to be generated and transmitted through federally compliant electronic prescribing systems.
- Set forth several exceptions to allow written and oral prescriptions.
- Specifically authorize the Commissioner to establish additional exceptions as necessary.

# Regulation Changes: Definitions

Amendments to 105 CMR 721.010, *Definitions*, implement the CARE Act by adding and amending several definitions relative to electronic prescriptions including:

- Adding Definitions for the following terms:
  - Compounded Drug Preparation, Electronic Prescribing System, Electronic Prescription, Electronic Transmission, ePrescribing, and Written Prescription
- Amending definitions were amended to conform with new requirements:
  - Electronic Signature and Registration Number

*These changes are necessary to implement electronic prescription requirements.*

# Regulation Changes: Prescription Formats

Amendments to 105 CMR 721.020, *Prescription Formats*, outline prescription formatting requirements for electronic prescriptions, as well as any written or oral prescriptions issued under one of the exceptions included at 105 CMR 721.070.

Proposed changes:

- Align with current information required on prescription forms; and
- Remove unnecessary requirements for prescription format, such as the order of fields on the prescription form.

*This change provides consistent standards to meet the goal of the law to reduce diversion and misuse.*

# Regulation Changes: Schedule VI Prescribers

Amendments to 105 CMR 721.030, *Security Standards for Prescriptions Issued by Prescribers Registered to Prescribe Schedule VI Controlled Substances Only*, set security requirements for Schedule VI prescriptions issued by prescribers registered to prescribe only Schedule VI medications.

Proposed changes:

- Maintain current prescription security requirements for Schedule VI prescriptions for those prescriptions issued under the exception in 105 CMR 721.070(A)(9).

*This change allows prescribers with Schedule VI only MCSR's to continue issuing prescriptions for Schedule VI medications on current systems.*

# Regulation Changes: Partial Fill Prescriptions

Amendments to 105 CMR 721.055, *Partial Fill Prescriptions*, implement Massachusetts' partial fill law, and amended by the CARE Act.

Proposed changes:

- Require a pharmacist to partially dispense a Schedule II prescription, if requested by a patient; and
- Allow a pharmacist to dispense the remaining portion of a partially filled prescription within 30 days of the prescription issue date.
  - As required by state law, the regulation specifies that the initial partial fill must take place within 5 days of the prescription issue date if the prescriber is out of state.

*This change provides patients the option to request a lesser amount of a medication, with the ability to fill the remainder .*

# Regulation Changes: ePrescribing and Emergency Situations

Amendments to 105 CMR 721.060, *ePrescribing and Emergency Situations* implement provisions of the CARE Act, which allow a Schedule II – VI substance to be dispensed upon written or oral prescription in emergency situations, as defined by the Commissioner.

Proposed changes:

- Defines emergency situations during which a prescriber is not required to issue an electronic prescription; and
- Moves requirements for orally prescribing and dispensing Schedule II medications in emergency situations to a new section, 105 CMR 721.065.

*This change recognizes situations where ePrescription requirements could result in a delay that would adversely impact the patient's medical condition.*



# Regulation Changes: Emergency Prescribing and Dispensing of Schedule II Controlled Substances

Amendments to 105 CMR 721.065, *Emergency Prescribing and Dispensing of Schedule II Controlled Substances* clarify the procedure for orally prescribing and dispensing an emergency Schedule II prescriptions in light of new electronic prescription requirements.

Proposed changes:

- Clarify that an oral prescription may be issued for Schedule II substances in emergency situations, during which a prescriber is not required to issue an electronic prescription;
- Set forth procedures for pharmacists to verify authorized oral prescriptions; and
- Outline procedures for prescribers to follow-up an oral prescription with an electronic prescription within 2 business days or a written prescription, when permitted, within 7 business days

*This change provides an option for emergency access to Schedule II medications, while maintaining appropriate controls.*

# Regulation Changes: ePrescribing Exceptions

Amendments to 105 CMR 721.070, *ePrescribing Exceptions*, are proposed to implement the CARE Act by outlining the statutory exceptions when electronic prescribing is not required, and four additional exceptions determined necessary to implement the ePrescribing law, while maintaining its intent to reduce diversion and fraud. The law also requires that any oral prescription issued under an exception be followed up with a written prescription within seven days.

Proposed changes outline statutory exceptions when written and oral prescriptions are permitted:

- prescriptions issued by veterinarians;
- prescriptions issued or dispensed during temporary technological or electrical failure;
- prescriptions issued pursuant to a time-limited waiver, based on economic hardship, technological limitations outside of practitioner’s control, or other exceptional circumstance;
- prescriptions issued or dispensed in emergency situations as defined by the Commissioner;
- Prescriptions that cannot be issued electronically under federal or state law or regulations; and
- prescriptions issued outside the jurisdiction of the commonwealth.

# Regulation Changes: ePrescribing Exceptions, cont.

M.G.L. c. 94C, § 23(h)(vii), as inserted by the CARE Act, authorizes the Commissioner to add exceptions determined necessary for implementation. These exceptions are based on engagement with prescribers and stakeholders, and research on ePrescribing challenges in other states.

Proposed changes:

- Set forth four necessary additional exceptions from ePrescribing that maintain drug safety and security:
  - Compounded drug preparations
  - Expedited Partner Therapy
  - Individuals with an MCSR for Schedule VI only; and
  - Durable Medical Equipment (DME)
- Outlines procedures for following-up an oral prescription with a written prescription.

*This change allows prescribers to issue written and oral prescriptions when ePrescribing is impractical, impossible or contradicts the intent of the law.*

# Regulation Changes: ePrescribing Exceptions – Compounded Drug Preparations

- Requiring electronic prescriptions for compounded drug preparations may prove impossible:
  - Federally-compliant electronic prescribing systems are designed to accommodate commercially available formulations and common dosing instructions.
  - Compounded drug preparations are custom formulated for the individual patient to include multiple drug components.
  - Federally-compliant systems cannot process the potentially infinite combinations and concentrations likely in a compounded preparation.
- In the last year, there were nearly 71,000 prescriptions for Schedules II-V compounded drug preparations reported to the PMP.
- This exception was strongly recommended by the Board of Registration in Pharmacy and is included as an exception from mandatory ePrescribing in several states, including New York, Iowa and Arizona.

# Regulation Changes: ePrescribing Exceptions – Expedited Partner Therapy

- ePrescribing defeats the purpose of M.G.L. c. 111, § 121B, which aims to prevent infection by authorizing prescribers to prescribe and dispense prescription drugs to a patient's sexual partners for the presumptive treatment of Chlamydia infection without an examination of the patient's sexual partners.
- Electronically prescribing this presumptive treatment
  - would require identification of a partner's receiving pharmacy, which may be unknown to the patient, and
  - may require identification of the partner's personal health information, which could discourage patients from claiming sexual partners.
- This exception is included as an exception from mandatory ePrescribing in several states, including Iowa and New York.

# Regulation Changes: ePrescribing Exceptions – Schedule VI-Only Prescribers

- This exception would allow Schedule VI ePrescribing, by prescribers that hold a Schedule VI-only MCSR, through current electronic systems that may not meet all federal security requirements.
- Upgrading or replacing a prescriber's current system with a federally compliant ePrescribing system would not meaningfully further the goal of reducing fraud and diversion.
  - Currently, ePrescribing of Schedule VI medications does not require a federally compliant system, as Schedule VI medications are not federally controlled, due to their limited potential for misuse and diversion.
- This exception would allow some Schedule II-VI prescribers, who only prescribe Schedule VI, to limit their MCSR to Schedule VI only, rather than upgrading to a federally compliant ePrescribing system.
- No other state applies its ePrescribing mandate to non-federally scheduled drugs.

# Regulation Changes: ePrescribing Exceptions – Durable Medical Equipment

- Medicaid coverage is provided for DME to allow patients to continue treatment at home and in the community.
- Hundreds of DME suppliers in Massachusetts accept prescriptions for purposes of insurance coverage, but are unlikely to have the capacity to accept electronic prescriptions.
- Additionally, electronic prescriptions for DME would not meaningfully contribute to the law's goal of improving drug security and reducing diversion.
- No other state with an ePrescribing requirement applies the mandate to devices, including DME.

# Regulation Changes: Time-Limited Waivers

Amendments to 105 CMR 721.075, *Time Limited Waivers of Electronic Prescribing Requirements*, establish a time-limited waiver process for prescribers and health care facilities as authorized by the CARE Act.

Proposed changes:

- Establishes a standard process for waiver application and approval, pursuant to statute, while protecting public health by requiring a demonstration of:
  - economic hardship;
  - technological limitations that are not reasonably within the prescriber's control; or
  - other exceptional circumstance
- Allows waiver requests to be filed by facilities, as well as individual prescribers, in recognition that many prescriptions are issued on systems owned and operated by hospitals and other health care facilities.

*This change allows flexibility for prescribers and facilities that are dealing with temporary circumstances that would not otherwise fit into a specific ePrescribing exception.*



# Next Steps

- Following this initial presentation, staff will hold a public hearing and comment period.
- Staff will review public comments and request approval of the proposed amendments at a subsequent meeting of the Public Health Council.



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# Massachusetts Department of Public Health

Thank you for the opportunity to present this information today.

For more information regarding prescription format and security, please find the relevant statutory language and the full current regulation here:

<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94C>

<https://www.mass.gov/files/documents/2017/09/11/105cmr721.pdf>

Please direct any questions to:

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